

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of the Secretary, Office of the Assistant Secretary of Health, Office of Population Affairs

FUNDING OPPORTUNITY TITLE: Announcement of Availability of Funds for Embryo Donation and/or Adoption Grant Projects.

ACTION: Notice

ANNOUNCEMENT TYPE: INITIAL COMPETITIVE GRANT

ANNOUNCEMENT NUMBER: OPA-2014-EA

CFDA NUMBER: 93.007

CFDA PROGRAM: Public Awareness Campaigns on Embryo Adoption

DATES:

Applications are due May 12, 2014 by 5 p.m. ET. To receive consideration, applications must be received by the HHS Office of the Assistant Secretary for Health (HHS/OASH), Office of Grants Management (OGM) no later than the applicable due date listed in this announcement (Section IV. 3, Submission Dates and Times) and within the time frames specified in the announcement. All applications for this funding opportunity must be submitted electronically through Grants.gov, and must be received by 5:00 PM Eastern Time on the applicable due date.

All applicants must submit in this manner unless they obtain a written exemption from this requirement 48 hours in advance of the deadline by the Director, HHS/OASH Office of

Grants Management. Applicants must request an exemption in writing via email from the HHS/OASH Office of Grants Management, and provide details as to why they are technologically unable to submit electronically through Grants.gov portal. Note: failure to have an active System for Account Management (SAM) registration will not be grounds for receiving a waiver to the electronic submission requirement. If requesting a waiver, include the following in the e-mail request: the HHS/OASH announcement number; the organization's DUNS number; the name, address and telephone number of the organization; the name and telephone number of the Project Director; the Grants.gov Tracking Number (GRANTXXXX) assigned to the submissions; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request to ogm.oash@hhs.gov.

The HHS/OASH Office of Grants Management will only accept paper applications from applicants that received prior written approval. However, the application must still be submitted by the deadline. No other submission mechanisms will be accepted. Applications which do not meet the specified deadlines will be returned to the applicant unread. See the heading "**APPLICATION and SUBMISSION INFORMATION**" for information on application submission mechanisms.

Executive Order 12372 comment due date: The State Single Point of Contact (SPOC) has 60 days from the application due date to submit any comments.

To ensure adequate time to successfully submit the application, HHS/OASH recommends that applicants register immediately in Grants.gov since the registration process can take up to one month. For information on registering for Grants.gov, refer to <http://www.grants.gov> or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Applicants are strongly encouraged to register multiple authorized organization representatives.

EXECUTIVE SUMMARY: The Office of Population Affairs, within the Office of the Assistant Secretary for Health (OASH) announces the availability of funds for Fiscal Year (FY) 2014 to support 3 to 5 new grant projects. This notice solicits applications for competing grant awards, with the goals of 1) increasing public awareness of embryo donation and/or adoption, or 2) providing "to individuals adopting embryos ...medical and administrative services, deemed necessary" for embryo donation/adoption. For the purposes of this announcement, counseling is considered a "medical service." "Administrative services" are those that help an embryo donation/adoption patient (or couple) to negotiate the process of embryo donation/adoption. OPA anticipates approximately \$775,000 will be available to support 1 to 3 new grants to promote public awareness as well as 1 to 3 new grants to promote embryo donation/adoption through the provision of services. Funding for each of the grants will range from \$100,000 to \$300,000 per year.

I. FUNDING OPPORTUNITY DESCRIPTION:

The increasing success of assisted reproductive technologies (ART) has enabled some infertile couples to create embryos through in-vitro fertilization (IVF) that are then cryopreserved (frozen) for future use. If a couple becomes pregnant without using all of the stored embryos, they may choose to donate the remaining embryos for use by other infertile couples. Embryo

donation is a relatively new process in which individuals with extra frozen embryos agree to release the embryos for use by another woman who wishes to achieve pregnancy. The recipient can be either anonymous or known to the donor(s).

OPA intends to fund at least one project in each of two distinct categories:

- Category 1 (Embryo Adoption and/or Donation Public Awareness Campaign) public awareness projects (including those that provide education for professionals who work in traditional adoption or in-vitro fertilization (IVF) to equip them with the specific knowledge and skills to support the unique needs of embryo donors and recipients; and
- Category 2 (Embryo Adoption and/or Donation Administrative or Medical Services) projects which provide administrative or medical services (including counseling) to patients who are in the process of embryo donation/adoption as well as those who may initiate a process of embryo donation or adoption in the near future. For the purposes of this announcement, training personnel to provide “medical or administrative services” falls within Category 2.

Entities may apply for both categories of funding; however, a separate application is required for each category identified in this announcement. For the purposes of this announcement, embryo donation and/or adoption is defined as the donation of frozen embryo(s) from one party to a recipient who wishes to bear and raise a child or children.

CATEGORY 1: OPA anticipates funding 1-3 projects that focus on increasing public awareness of embryo donation and/or adoption. This category comprises traditional media and advertising

modalities, "new media" efforts (such as blogging) as well as generalized education in the basic principles of embryo donation/adoption that can be offered to large audiences. Category 1 applicants should make reasonable efforts to ensure that the individuals who design and implement the public awareness projects are knowledgeable in all facets of the embryo donation and/or adoption process and are experienced in providing such information.

Applicants are encouraged to incorporate, to the extent possible, the concepts of Reproductive Life Planning in their public awareness messaging. Reproductive Life Planning (RLP) is a process by which an individual 1) establishes goals about the number and spacing of children that she or he wants; and, 2) marshals resources (including physical health and time) in an effort to meet those goals. More information about RLP is available at www.cdc.gov/preconception/reproductiveplan.html.

Applicants are also encouraged to develop a plan to counter common misconceptions about frozen embryo adoption that appear in traditional and social media (e. g. that frozen embryos only remain viable for a limited time) by employing recent findings from the medical, legal and social science literature.

In the narrative section of the application for this category, applicants are advised to describe the strategies and processes that they will use to design a public awareness campaign. The applicant should document its capacity to undertake an awareness campaign focused on the general public or on professional audiences. Applicants are encouraged to present a description of approaches that will be employed, as well as any supplemental materials (resource manuals, brochures, handouts, visual aids, and other resources) that will be used.

CATEGORY 2: OPA anticipates funding 1 to 3 projects that will provide administrative and/or medical services—including counseling—to couples who are currently or potentially involved in embryo donation or adoption. For the purposes of this announcement, counseling is considered a “medical service.” “Administrative services” are those that help an embryo donation/adoption patient (or couple) to negotiate the financial, legal and other non-medical aspects of the process of embryo donation/adoption. Training of professionals, for the purpose of enabling them to provide administrative and/or medical services, is also within the scope of permissible activities

In the narrative section of the application, applicants are advised to describe in detail the means they intend to use to assist couples who are in the process of embryo donation or adoption. Applicants are encouraged to develop strategies for delivering services that increase the ability of couples to donate or adopt frozen embryos. Strategies aimed at increasing the percentage of currently frozen embryos that are made available for donation/adoption are acceptable under this program. In particular, the applicants are urged to devise strategies that “front load” services such as counseling so as to provide early information about the advantages (and disadvantages) of embryo donation/adoption to infertile couples. In other words, applicants in this category are advised to develop counseling interventions that approach infertile couples who may be considering embryo donation/adoption before they actually commence the process of in vitro fertilization. For the purposes of this Funding Opportunity Announcement, applicants are advised to develop approaches that inform infertile couples who may be considering embryo donation/adoption about the possibilities and costs of embryo donation/adoption early in the couple’s infertility journey. To this end, projects involving Ob/Gyn medical practices are encouraged.

Projects that support administrative services for people who have decided to participate in embryo donation/adoption are also included in Category 2. A project that proposes a call-in center to give specific information on State and Federal regulations pertaining to frozen embryo transfer would be an example of a Category 2 project to provide administrative services.

Embryo donation and/or adoption is an emerging field. The practice of embryo donation and/or adoption is complicated by the different attitudes and expectations that professionals, as well as potential donors, have about this option. Many potential donors have limited knowledge of embryo donation and little access to information to aid them in making a decision on the donation of their embryos. Potential donors may benefit from the provision of information and connection to support networks or peers. OPA is interested in assisting potential donors with this difficult decision and in providing training to professionals for the purpose of preparing them to provide supportive services to potential donors. The current and emerging body of knowledge related to embryo donation and/or adoption should provide the basis for training content.

Successful applicants will be able to incorporate current, evidence-based information in all phases of training design, delivery, and evaluation. Applicant organizations should demonstrate significant experience in the design, development, implementation, successful completion, and evaluation of training activities. In addition, the successful applicant must demonstrate skill and experience in providing training to diverse groups. The successful applicant will provide evidence of familiarity with embryo donation and/or adoption and the ability to translate evidence-based information into focused training activities.

Applicants funded under this category are permitted to conduct training activities for professionals that offer couples or individuals help with the medical, legal, psycho-social, ethical, and practical issues surrounding embryo donation and/or adoption. This training should

be designed to enhance the ability of multiple levels of providers to share information and to assist potential donors with embryo donation and/or adoption. Training design and content should be adjusted to the skill and practice role of the target audience. OPA expects that appropriate continuing education credits will be available for training activities provided under this announcement. The content and number of offerings should be based on an assessment of the need and these offerings should be designed and delivered in a manner appropriate to the content of the course as well as professional preparation of the participants. Distance learning strategies may be incorporated as part of the training offerings.

Applicants are encouraged to devise strategies to identify the various professional audiences associated with embryo donation and/or adoption and to provide training to the involved professionals (e.g., reproductive medicine physicians, nurses, embryologists, family practice lawyers, adoption counselors, ethicists, social workers, IVF clinic staff, embryo storage facility staff, etc.) in the complex legal, medical, psycho-social, ethical and practical issues that confront the embryo donor and recipient populations.

Services offered by Category 2 applicants must be offered consistent with 42 CFR 59.5(a)(4), which requires that services be provided “without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.” Applicants are advised to demonstrate a familiarity with, and understanding of, professionally recognized standards or practices (both medical and legal) pertaining to embryo donation and/or adoption, as well as supportive services for potential donor or recipient couples. The applicant organization should clearly demonstrate its professional knowledge and experience with potential donor or recipient populations.

The applicant should document its capacity to undertake a grant project that offers medical or administrative services to couples involved in embryo donation/adoption. Applicants are encouraged to present a description of approaches which they propose to use in their service delivery. These approaches should be economically feasible, equitable and ethically sound.

Project funds cannot be used to pay for human tissues, nor for any approach that may be construed as involving compensation for the donation of human tissues. Reimbursement of a donor's already accrued storage fees is not considered an acceptable practice under this program.

AUTHORITY: This program is authorized by Division H, Title II of the Consolidated Appropriations Act, 2014 (Public Law No. 113-76).

II. AWARD INFORMATION

The Office of Population Affairs intends to make available approximately \$775,000 for 3-5 competing grants. Grants will be funded in annual increments (budget periods) and may be approved for a project period of up to 2 years, although shorter project periods may be approved. Funding for all approved budget periods beyond the first year of the grant is contingent upon the availability of funds, satisfactory progress of the project, and adequate stewardship of Federal funds.

Award Information

Estimated Funds Available for Competition: \$775,000

Anticipated Number of Awards: 3-5

Range of Awards: \$100,000-\$300,000

Anticipated Start Date: 08/1/2014

Period of Performance: Not to exceed 2 years

Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov **ONLY unless a waiver is granted**

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

Only agencies and organizations, not individuals, are eligible to apply. Eligible applicants include public agencies, non-profit organizations or for-profit organizations. Educational institutions—including academic medical centers and/or their affiliated clinics—are eligible to apply for this grant. American Indian/Alaskan Native/Native American (AI/AN/NA) organizations are also eligible to apply. One agency must be identified as the applicant organization and this agency will have legal responsibility for the project.

Additional agencies and organizations can be included as co-participants, subgrantees, subcontractors, or collaborators if they assist in providing expertise and in helping to meet the needs of the recipients.

Applicants should note that section 45 CFR Part 74.81 of the DHHS Uniform Administrative Requirements indicate that, except for awards under certain small business

programs, no grant funds may be paid as profit to any recipient even if the recipient is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.

Only those organizations or agencies that demonstrate the capability of providing the proposed services and that meet the requirements of this announcement will be considered for awards. Applications are encouraged from organizations that are currently operating programs that have the capability of providing services (including counseling) to people who are considering embryo donation and/or adoption. Moreover, applications are encouraged from organizations that have the capability to conduct a rigorous evaluation of the funded project.

Faith-based and community-based organizations that meet the eligibility requirements are eligible to apply for these embryo donation and/or adoption grant projects. Please note, however, that grant funds may not be used for inherently religious activities, such as worship, religious instruction, and proselytization. If an organization engages in such activities, they must be offered separately in time or location from the grant program and participation must be voluntary for program beneficiaries. In providing services and outreach related to program services, a funded entity may not discriminate against current or prospective program beneficiaries on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

2. *Cost Sharing or Matching*: none

Application Screening Criteria

All applications will be screened to assure a level playing field for all applicants.

Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via www.grants.gov (unless a waiver has been granted) by May 12, 2014.
2. The Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.
3. The Project Narrative must not exceed 35 pages. NOTE: The following items do not count toward the page limit: required forms, including SF 424 and SF 424A, Budget justification and/or budget narrative;
4. The total application including appendices must not exceed 60 pages.
5. Proposed budget does not exceed maximum indicated in Range of Awards.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Information to Request Application Package

Application kits may be obtained electronically by accessing Grants.gov at <http://www.grants.gov/>. If you have problems accessing the application or difficulty downloading, contact:

Grant Operations Center, Office of Grants Management Operations Center, telephone 1-888-203-6161, or email ASH@LCGnet.com.

2. Content and Form of Application Submission

Applications must be prepared using forms and information provided in the online application kit.

The application narrative must be limited to no more than 35 double-spaced pages, and the total application, including appendices, may not exceed the equivalent of 60 8 ½” x 11” pages when printed by HHS/OASH/OGM.

The applicant should use an easily readable typeface, such as Times New Roman or Arial, 12-point font. Tables may single spaced and use alternate fonts but must be easily readable. The page limit does not include budget, budget justification, required forms, assurances, and certifications. All pages, charts, figures, and tables should be numbered, and a table of contents provided. Applications that exceed the specified limits of 60 pages when printed by HHS/OASH/OGM will be deemed non-responsive and will not be considered. It is recommended that applicants print out their applications before submitting electronically to ensure that they are within the page limit.

Appendices may include curriculum vitae, organizational structure, examples of organizational capabilities, or other supplemental information which supports the application. Brochures and bound materials should not be submitted. Appendices are for supportive information only and should be clearly labeled. All information that is critical to the proposed project should be included in the body of the application. Appendices created for the application should use the formatting required for the narrative. Appendices from other sources and documents may use other formatting but must be easily readable.

For all non-profit organization applicants, documentation of nonprofit status must be submitted as part of the application. Any of the following constitutes acceptable proof of such status:

1. A reference to the Applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code;
2. A copy of a currently valid IRS tax exemption certificate;
3. A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; or
4. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.

For local, nonprofit affiliates or State or national organizations, a statement signed by the parent organization indicating that the applicant organization is a local nonprofit affiliate must be provided in addition to any one of the above acceptable proof of nonprofit status.

Applications must include an abstract of the proposed project. The abstract will be used to provide reviewers with an overview of the application, and will form the basis for the application summary in grants management documents.

The HHS Office of the Assistant Secretary for Health (HHS/OASH) requires that all applications be submitted electronically via the Grants.gov portal unless a waiver has been granted. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, *will not* be accepted for review.

You may access the Grants.gov website portal at <http://www.grants.gov>. All HHS/OASH funding opportunities and application kits are made available on Grants.gov.

Applications will not be considered valid until all electronic application components are received by the HHS/OASH Office of Grants Management according to the deadlines specified above. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process. This will aid in addressing any problems with submissions prior to the application deadline. Any files uploaded or attached to the Grants.gov application must be of the following file formats – Microsoft Word, Excel or PowerPoint, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only). Even though Grants.gov allows applicants to attach any file format as part of their application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format identified above will not be accepted for processing and will be excluded from the application during the review process. The application must be submitted in a file format that can easily be copied and read by reviewers. It is recommended that scanned copies not be submitted through Grants.gov unless the applicant confirms the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. All documents that do not conform to the above will be excluded from the application during the review process.

A. Important Grants.gov Information

Electronic submission via Grants.gov is a two-step process. Upon completion of a successful electronic application submission via the Grants.gov Website Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (Eastern Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is

critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Website Portal then will be validated by Grants.gov. Any applications deemed “Invalid” by the Grants.gov Website Portal will not be transferred to HHS/OASH, and HHS/OASH has no responsibility for any application that is not validated and transferred to HHS/OASH from the Grants.gov Website Portal. Grants.gov will notify the applicant regarding the application validation status.

You will initially receive a notice that your application has been received by Grants.gov and is being validated. Validation may take up to 2 business days. You will receive a notice via email when your application has been validated by Grants.gov and is ready for the HHS/OASH to retrieve and review. If your application fails validation it will **not** be accepted for review. Therefore, **you should submit your electronic application with sufficient time to ensure that it is validated in case something needs to be corrected.**

Applicants should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through the Grants.gov Website Portal.

- You may access the electronic application for this program on <http://www.grants.gov>. You must search the downloadable application page by the Funding Opportunity Number or CFDA number.
- At the <http://www.grants.gov> website, you will find information about submitting an application electronically through the site, including the hours of operation. HHS/OASH strongly recommends that you do not wait until the application due date to begin the application process through <http://www.grants.gov> because of the time involved to complete the registration process.

- Since October 1, 2003, the Office of Management and Budget has required applicants to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. It is entered on the SF 424. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or by using this link to access a guide: https://www.whitehouse.gov/omb/grants/duns_num_guide.pdf. Instructions are also available on the Grants.Gov web site as part of the registration process.
- All applicants must register in the System for Account Management (SAM) (formerly the Central Contractor Registry (CCR)). You should allow a minimum of five days to complete the SAM registration. Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You can register with the SAM online and it will take about 30 minutes (<http://sam.gov>.)

You must renew your SAM registration each year. Organizations registered to apply for Federal grants through <http://www.grants.gov> will need to *renew* their registration with the SAM. It may take 24 hours or more for updates to take effect, so potential applicants should ***check for active registration well before the application deadline.***

- Effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive Federal grant funds from any HHS Operating/Staff Division (OPDIV/STAFFDIV) or receive sub-awards directly from the recipients of those grant funds to:
 1. Be registered in the SAM prior to submitting an application or plan;
 2. Maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV; and
 3. Provide its DUNS umber in each application or plan it submits to the OPDIV.

An award cannot be made until the applicant has complied with these requirements. At the time an award is ready to be made, if the intended recipient has not complied with these requirements, the OPDIV/STAFFDIV:

- May determine that the applicant is not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Additionally, all first-tier sub-award recipients must have a DUNS number at the time the sub-award is made.

- You must submit all documents electronically, including all information included on the SF-424 and all necessary assurances and certifications.
- Prior to application submission, Microsoft Vista and Office 2007 users should review the <http://www.grants.gov> compatibility information and submission instructions provided at <http://www.grants.gov> (click on “**Vista and Microsoft Office 2007 Compatibility Information**”).

- Your application must comply with any page limitation requirements described in this Program Announcement.
- **Attachment Filename Characters are now Validated and Enforced:**
 - Beginning August 15, 2012, applicants are now limited to using the following characters in all attachment file names.
 - Valid file names may only include the following **UTF-8 characters:**
 - **A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.**
 - **If applicants use any other characters when naming their attachment files their applications will be rejected.**

B. Application Content

Successful applications will contain the following information:

Project Narrative

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether or not your project meets the minimum requirements for a grant under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

- 1) Project Summary/Abstract: Provide a summary of the project not to exceed one page.

Care should be taken to produce an abstract/summary that accurately and concisely reflects the proposed project since the abstract will be used to provide reviewers with an overview of the application and will form the basis for an application summary in official documents. The abstract should describe the objectives of the project, the approach to be used and the results or benefits expected. This project summary may be posted on the OPA website if the project is awarded a grant.

2) Need for Assistance: Demonstrate a clear understanding of the program goals and explain how the particular approach to the project and objectives will contribute to achieving these goals. Clearly identify the physical, economic, social, legal, financial, institutional and/or other problem(s) requiring a solution. The need for assistance should be demonstrated and the principal and subordinate objectives of the project should be clearly stated. Outline the specific geographic region that will be served by the organization. This section should include a justification for the selection of the region, based on, for example, geographic size or the number and types of Assisted Reproductive Technology (ART) centers in the area. Note that grant funds may only be used for domestic purposes and activities. Describe the rationale for use of the proposed approach based upon previous practice and review of the literature and/or evaluation findings. Any relevant data based on studies should be included or referred to in the proposed approach and referred to in the endnotes/footnotes.

3) Approach and Objectives: The applicant should provide a detailed work plan and timetable as well as goals and objectives that are specific, measurable, achievable, realistic and time-framed (SMART) for the proposed project. Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions and activities identified in the application. Cite factors that might accelerate or decelerate the work, and state reasons for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and/or community involvement. Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of program activities to be held, or appropriate measurable outcomes. When

accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of the accomplishments and their target dates.

4) Evaluation: Provide a narrative addressing how results of the project and conduct of the project will be evaluated. In addressing the evaluation of results, the successful applicant will determine the extent to which the project has achieved its stated objectives and the extent to which this accomplishment of objectives can be attributed to the action of the project. The evaluation should be based on a logic model that visually links the program interventions to the program's objectives. The applicant should discuss the criteria used to evaluate results, and explain the methodology that will be used to decide if the identified needs are being met and if the project results are being achieved.

With respect to the conduct of the project, the applicant should define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness. For service grants that offer counseling, project effectiveness will be evaluated by the number of couples given counseling as well as by the number of couples making decisions to donate their embryos for adoption.

Applicants that do not have the in-house capacity to conduct an evaluation are advised to propose contracting with a third-party evaluator to conduct the evaluation.

5) Organizational Profiles: Provide information on the applicant organization and cooperating partners such as organizational charts, documentation of professional accreditation, documentation of experience in the program area, and other pertinent information. Applicants should demonstrate an understanding of the intended audience as well as the information and

skills needed by the designated staff. Applicants are advised to show that they have the organizational capacity and resources to carry out the project on time and to a high standard of quality, including the capacity to resolve a variety of technical and management problems that may occur. Capacity includes: 1. Previous experience with similar projects; 2. Experience with the target audience; 3. Qualifications and experience of the project leadership, including those who are consultants or subcontractors; and, 4. Suitability of the organizational structure for the proposed project. Applicants are expected to present a feasible management plan for implementing the proposed program. This section should detail how the program will be structured and managed, how timeliness of activities will be ensured, how quality will be maintained, and how costs will be controlled. The role and responsibilities of the lead agency should be clearly defined and applicants should describe the management and coordination of activities carried out by any partners, subcontractors or consultants.

6) Budget and Budget Justification: Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs. Identify the project director or principal investigator, if known. For each staff person, provide the title and time commitment to the project (as a percentage of a full-time equivalent). Include the costs of consultants or personnel, costs of sub-recipients or of specific project(s) to be financed by the applicant. Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, and taxes, unless treated as part of an approved indirect cost rate. Include information on the costs of project-related travel by employees of the applicant organization (not including costs of consultant travel). For each trip, show the total number of travelers, travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other

transportation costs and subsistence allowances. Applicants are expected to allocate sufficient funds in the budget to provide for one teleconference with the project officer and other grantees during the performance of the project. For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use of the equipment in the project, as well as use or disposal of the equipment after the project ends. List general categories of supplies and their costs. Show computations and provide other information, which supports the amount requested. Include information on the costs of all contracts for services and goods except for those, which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary recipient organizations should be included under this category.

3. Submission Dates and Times

The deadline for the submission of applications under this Program Announcement is **5:00 p.m. Eastern Time on May 12, 2014**. Applications must be submitted by that date and time.

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <http://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful submission.

Unsuccessful submissions will require authenticated verification from <http://www.grants.gov> indicating system problems existed at the time of your submission. For example, you will be required to provide an <http://www.grants.gov> submission error notification and/or tracking number in order to substantiate missing the cut off date.

Grants.gov (<http://www.grants.gov>) will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in <http://www.grants.gov>.

4. Intergovernmental Review

Applications under this announcement are subject to the requirements of Executive Order 12372, “Intergovernmental Review of Federal Programs,” as implemented by 45 CFR part 100, “Intergovernmental Review of Department of Health and Human Services Programs and Activities.” As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for the State in which the applicant is located. The application kit contains the currently available listing of the SPOCs that have elected to be informed of the submission of applications. For those states not represented on the listing, further inquiries should be made by the applicant regarding submission to the relevant SPOC. The SPOC should forward any comments to the Department of Health and Human Services, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH Office of Grants Management at 240-453-8822.

5. Funding Restrictions

The allowability, allocability, reasonableness and necessity of direct and indirect costs that may be charged to HHS/OASH grants are outlined in the following documents: 2 CFR § 220 (OMB Circular A-21, for Institutions of Higher Education); 2 CFR § 225 (OMB Circular A-87, for State, Local, and Indian Tribal Governments); 2 CFR § 230 (OMB Circular A-122, for Nonprofit Organizations); and 45 CFR part 74, Appendix E (Hospitals). Copies of the Office of

Management and Budget (OMB) Circulars are available on the Internet at

<http://www.whitehouse.gov/omb/circulars/>.

In order to claim indirect costs as part of a budget request, an applicant must have an indirect cost rate which has been negotiated with the Federal Government. The Health and Human Services Division of Cost Allocation (DCA) Regional Office that is applicable to your State can provide information on how to receive such a rate. A list of DCA Regional Offices is included in the application kit for this announcement.

Salary Limitation:

The Consolidated Appropriations Act, 2014 (P.L. 113-76) limits the salary amount that may be awarded and charged to HHS/OASH grants and cooperative agreements. Award funds should not be budgeted to pay the salary of an individual at a rate in excess of Executive Level II. Currently, the Executive Level II salary of the Federal Executive Pay scale is \$181,500. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HHS/OASH grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is \$350,000 per year plus fringe benefits of 25% (\$87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to \$181,500, their direct salary would be \$90,750 (50% FTE), fringe benefits of 25% would be \$22,687.50, and a total of \$113,437.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

| |
|---|
| Individual's <i>actual</i> base full time salary: \$350,000 |
|---|

| | |
|---|---------------------|
| 50% of time will be devoted to project | |
| Direct salary | \$175,000 |
| Fringe (25% of salary) | \$43,750 |
| Total | \$218,750 |
| <p>Amount that may be claimed on the application budget due to the legislative salary limitation:</p> <p>Individual's base full time salary <i>adjusted</i> to Executive Level II: \$181,500</p> <p>50% of time will be devoted to the project</p> | |
| Direct salary | \$90,750 |
| Fringe (25% of salary) | \$22,687.50 |
| Total amount | \$113,437.50 |

Appropriate salary limits will apply as required by law.

6. Other Submission Requirements:

Applicants must indicate in the first line of the Abstract whether the proposed activities constitute a Public Awareness Project (i.e. Category 1) or a Services Project (i.e. Category 2).

V. APPLICATION REVIEW INFORMATION

1. Criteria: Eligible applications will be assessed according to the following criteria:

Criterion 1: Project Summary/Abstract (5 Points)

Applicants are expected to summarize the proposed project in an abstract not to exceed one page. The abstract must include the project's objectives, its approach and the results or benefits that are expected from the project.

Criterion 2: Need for Assistance (25 Points)

Specific considerations for this section include: (1) The extent to which the application reflects an understanding of: (a) the goals of the public awareness campaign for embryo donation and/or adoption, and how implementation will contribute to achieving these goals; or (b) The extent to which the application reflects a knowledge and understanding of the challenges involved with offering services to facilitate embryo donation and/or adoption; (2) The extent to which the application clearly describes and documents the need for assistance to enhance efforts to: a) increase public awareness of embryo donation and/or adoption; or, (b) make services, including counseling, available to people that are currently involved (or soon may be involved in) the process of embryo donation or adoption; (3) The extent to which the application reflects an understanding of the medical and legal framework of embryo donation and/or adoption, and the services and resources in the geographic area in which the proposed project will be conducted; (4) The extent to which the application explains how the proposed project will contribute to increased knowledge of the problems, issues, and effective strategies and best practices in the field of embryo donation and/or adoption; and (5) The extent to which the application presents a vision of how the project will advance: (a) public awareness of embryo donation and/or adoption, or, (b) the ability of couples to use embryo donation/adoption services; and, (6) The extent to which the applicant discusses the broad contextual factors that will facilitate or impede the project.

Criterion 3: Approach and Objectives (30 Points)

In this section, applicants are expected to define goals and specific, measurable objectives for the project. Goals are an end product of an effective project. Objectives are measurable steps for reaching goals and should be specific, measurable, achievable, realistic and time-framed (SMART). Applicants are advised to describe a preliminary, yet appropriate and feasible work plan pertaining to the scope of the proposed project and provide details on how the proposed project will be accomplished. If the project involves partnerships with other agencies and organizations, then the roles of each partner should be clearly specified.

Applicants should describe the activities that they will develop pursuant to the project. Applicants should discuss the intended audiences for these activities (e.g., ART centers, Ob-Gyn practices, adoption organizations, professional organizations that work with infertile couples, embryo storage facilities, potential recipients, or donors) and present a dissemination plan specifying the venues for conveying the information. This criterion consists of three broad topics: (A) project design, (B) implementation, and (C) dissemination. Specific considerations for this criterion include:

(A) Design of the Project:

(1) The extent to which the application reflects a familiarity with and understanding of professionally recognized standards and/or other relevant Federal or State requirements pertaining to embryo donation and/or adoption.

(2) The extent to which the proposed project goals, objectives, and outcomes are clearly specified and measurable, and reflect an understanding of the context, and

(3) The extent to which the application presents an approach that: (a) is competency based; and, (b) can be evaluated.

(B) Implementation of the Project:

(1) The extent to which the application clearly describes and provides a justification for the selection of the geographic region that will be served by the project;

(2) The extent to which the application presents an appropriate, feasible, and realistic plan for conducting the project;

(3) The extent to which the application presents an appropriate, feasible and realistic plan for recruiting, selecting, and training individuals to conduct the project;

(4) The extent to which the application provides an appropriate, feasible and realistic plan for documenting project activities and results, that can be used to describe and evaluate the project, and participant satisfaction; and,

(5) The extent to which the proposed project will establish and coordinate linkages with other appropriate agencies and organizations.

(C) Dissemination of the Project:

(1) The extent to which the application provides an appropriate, feasible and realistic plan for dissemination of information and related educational materials;

(2) The extent to which the intended audience is clearly identified and defined and is appropriate to the goals of the proposed program;

(3) The extent to which the program's products will be useful to the respective audiences;

(4) The extent to which the applicant presents a realistic schedule for developing these products, and provides a dissemination plan that is appropriate in scope and budget to each of the audiences; and,

(5) The extent to which the products being developed during the program are described clearly and will address the goal of dissemination of information and are designed to support evidence-based improvements of practices in the field.

Criterion 4: Evaluation (20 Points)

Applicants should describe how the project will be evaluated so as to determine the extent to which it has achieved its stated goals and objectives. Applicants are expected to present a project design that includes detailed procedures for documenting project activities that is sufficient to implement goals and provide for an evaluation. The evaluation designs are expected to include process and outcome analyses if feasible. Service projects that provide counseling should have a record keeping system that enables them to keep track of the number of couples counseled as well as the number of couples who decide to donate their embryos. Grantees must report on their evaluation results in their final report to the OPA upon completion of the project period.

Applicants are expected to present evaluations which provide (A) a logic model that visually links the program interventions to the program objectives and (B) clear descriptions of the process and outcome evaluation which include:

(1) The extent to which the methods of evaluation are feasible, comprehensive, and appropriate to the goals, objectives, and context of the project;

(2) The extent to which the applicant offers an appropriate, feasible, and realistic plan for evaluating the project, including performance feedback and assessment of program progress that can be used as a basis for program adjustments;

(3) The extent to which the methods of evaluation include process and outcome analyses, as appropriate, for assessing the effectiveness of the program strategies and implementation process; and,

(4) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the program and which will produce quantitative and qualitative results.

Criterion 5: Organizational Profile (10 Points)

This criterion consists of three broad topics: (A) organizational capacity and resources, (B) staff qualifications, and (C) management plan. This section should demonstrate the staff's knowledge of the medical and legal issues concerning embryo donation and/or adoption, and experience working in this area. Brief resumes of current and proposed staff, as well as job descriptions, should be included. Resumes should indicate the position that the individual will fill, and each position description should specifically describe the job as it relates to the proposed project. If the proposed project involves partnering and/or subcontracting with other agencies/organizations, then the application should include an organizational capability statement for each participating organization documenting the ability of the partners and/or

subcontractors to fulfill their assigned roles and functions. Specific considerations for this criterion include:

(A) Organizational Capacity and Resources

(1) The extent to which the management plan presents a realistic approach to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, time lines and milestones for accomplishing project tasks;

(2) The extent to which the role and responsibilities of the lead agency are clearly defined and the time commitments of the project director and other key project personnel (including consultants) are appropriate and adequate to meet the objectives of the proposed project; and,

(3) The extent to which the applicant discusses factors that may affect the development and implementation of the project and presents realistic strategies to resolve these difficulties.

(B) Staff Qualifications

(1) The extent to which the proposed project director, key project staff, and consultants have the necessary technical skill, knowledge, and experience to carry out their responsibilities; and,

(2) The extent to which staffing is adequate for the proposed project, including administration, program services, data processing and analysis, evaluation, reporting and implementation of the project.

(C) Management Plan

Applicants should provide letters of commitment or Memoranda of Understanding from organizations, agencies, and consultants that will be partners or collaborators in the proposed project. These documents should describe the role of each agency, organization, or consultant and detail specific tasks to be performed.

Criterion 6: Budget and Budget Justification (10 Points)

Applicants are expected to present a detailed budget for both budget years. The budget should present reasonable project costs, appropriately allocated across component areas and sufficient to accomplish the objectives. Consideration shall be given to project delays due to start-up when preparing the budget. Specific considerations for this criterion include:

(1) The extent to which the applicant demonstrates that the project costs and budget information submitted for the proposed program are reasonable and justified in terms of the proposed tasks and the anticipated results and benefits; and,

(2) The extent to which the fiscal control and accounting procedures are adequate to ensure prudent use, proper and timely disbursement, and an accurate accounting of funds received under this announcement.

2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that pass the screening criteria. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the

Application Review Criteria as outlined under [Section V.1], the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

Final award decisions will be made by the Deputy Assistant Secretary for Population Affairs or her designee

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The HHS Office of the Assistant Secretary for Health does not release information about individual applications during the review process. When final funding decisions have been made, each applicant will be notified by letter of the outcome. The official document notifying an applicant that a project application has been approved for funding is the Notice of Award (NOA), approved by the Director of the HHS/OASH Office of Grants Management. This document specifies to the grantee the amount of money awarded, the purposes of the grant, the anticipated length of the project period, terms and conditions of the grant award, and [the amount of funding to be contributed by the grantee to project costs if needed]. Grantees should pay specific attention to the terms and conditions of the award as indicated on the NOA, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the grant.

2. Administrative and National Policy Requirements

In accepting the grant award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 45 CFR parts 74 and 92, currently in effect or implemented during the period of the grant.

In addition, recipients must comply with all terms and conditions outlined in their grant awards, the Department of Health and Human Services (HHS) Grants Policy Statement, requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts.

Grant funds may only be used to support activities outlined in the approved project plan. The successful applicant will be responsible for the overall management of activities within the scope of the approved project plan. The HHS/OASH strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

Federal grant support must be acknowledged in any publication developed using funds awarded under this program. All publications developed or purchased with funds awarded under this program must be consistent with the requirements of the program. Pursuant to 45 CFR § 74.36(a), HHS may reproduce, publish, or otherwise use materials developed under this grant for Federal purposes, and may authorize others to do so.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable

to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at http://dhhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html.

Pilot Whistleblower Protection

A standard term and condition of award will be in the final notice of award; all applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award, and requires that grantees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

Reporting

Programmatic Reporting

Grantees are required to submit semi-annual programmatic reports. A final progress report covering the entire project period is due 90 days after the end of the project period. If a second year of funding is offered under this FOA, an annual progress report will be required as part of the continuation application.

Financial Reporting

Grantees are required to submit quarterly and annual Federal Financial Reports (FFR). Reporting schedules will be issued as a condition of grant award. A final FFR covering the entire project period is due 90 days after the end of the project period.

Grantees that receive \$500,000 or greater of Federal funds must also undergo an independent audit in accordance with OMB Circular A-133.

Each year of the approved project period, grantees are required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year.

FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

VII. AGENCY CONTACTS

Administrative and Budgetary Requirements and Program Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH Office of Grants Management grants specialist listed below.

Deborah Hayes

1101 Wootton Parkway, Suite 550

Rockville, MD

Phone: 240-453-8822

Email: Deborah.Hayes@hhs.gov

For information on program requirements, contact the program office.

Robert Scholle

1101 Wootton Parkway, Suite 700

Rockville, MD

Phone: 240-453-2848

Email: Robert.Scholle@hhs.gov

VIII. OTHER INFORMATION

1. Application Elements

SF 424 – Application for Federal Assistance

SF 424A – Budget Information

Separate Budget Narrative/Justification

SF 424B – Assurances.

Lobbying Certification

Proof of non-profit status, if applicable.

Copy of the applicant's most recent indirect cost agreement, if requesting indirect costs. If any sub-contractors or sub-grantees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

Project Narrative with Work Plan

Organizational Capability Statement and Vitae for Key Project Personnel.

Letters of Commitment from Key Partners, if applicable.

Susan B. Moskosky

_____, 2014

Acting Director

Office of Population Affairs